REMARKS

The instant Amendment and Response is being submitted concurrently with a Request for Continued Examination.

Statement of Substance of Interview Under 37 C.F.R. § 1.133(b)

In accordance with 37 C.F.R. § 1.133(b) and M.P.E.P. § 713.04, Applicants herein provide a summary of a telephonic interview between Applicants' representative and Examiner Snedden conducted on April 18, 2005 ("the interview"). Applicants thank Examiner Snedden for agreeing to conduct an interview and appreciate the courtesies extended by the Examiner.

During the interview, Examiner Snedden and Applicants' representative discussed U.S. Patent No. 5,670,340, issued to Yabuta et al. ("the Yabuta '340 patent"). In particular, the Examiner agreed that Example 3 of the Yabuta '340 patent did not teach a method for reducing formation of a byproduct polypeptide comprising an O-acetylserine residue in place of a serine residue comprising: culturing, in a medium, transformed host cells that produce a recombinant atrial natriuretic peptide comprising a serine residue and a byproduct polypeptide comprising an O-acetylserine residue in place of a serine residue; adding to said medium at least one of histidine, methionine or glycine in an amount effective to reduce said byproduct formation; and reducing the formation of said byproduct polypeptide.

Amendments to the Claims

Reconsideration of this application is respectfully requested. Upon entry of the foregoing amendment, claims 3-6 and 8-12 remain pending in the application. Claims 6 and 8-11 are currently amended, claim 12 is newly added and claim 7 is canceled.

Applicants respectfully request entry of the above amendment and submit that the above amendment does not constitute new matter. Support for amended claims 6 and 8-11 and newly added claim 12 can be found throughout the specification and in the claims as originally filed. In particular, support for the amendment to claim 6 can be found on page 11, ll. 14-15 of the specification. Support for the amendments to claims 8-11 can be found, for example, in the

abstract, specification at page 12, ll. 1-13, Example 3 and claims 9-11 of the preliminary amendment filed on January 10, 2002. Support for claim 12 can be found on page 19 of the specification.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding rejections and that they be withdrawn.

Rejections under 35 U.S.C. § 102(b)

Claims 3-11 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,670,340, issued to Yabuta et al. Applicants respectfully traverse this rejection.

Anticipation can be established only by a single reference that discloses each and every element of the claimed invention. *See Structural Rubber Prods. Co. v. Park Rubber Co.*, 749 F.2d 707, 716, 223 U.S.P.Q. 1264, 1270 (Fed. Cir. 1984); M.P.E.P. § 2131 at 2100-73 (8th ed., Rev. No. 2). If a single element required by the claim is missing in the reference, there can be no anticipation. *See Structural Rubber*, 749 F.2d at 707, 223 U.S.P.Q. at 1271-72.

At the outset, Applicants note that claim 7 has been canceled by the current amendment, and the limitation of claim 7 has been incorporated into claims 9-10. Furthermore, Applicants respectfully submit that the Yabuta '340 patent does not teach each and every element of currently amended claims 9-11 or the dependent claims thereof.

As discussed with the Examiner during the telephonic interview of April 18, 2005, the Yabuta '340 patent does not disclose a method for reducing formation of a byproduct polypeptide comprising an O-acetylserine residue in place of a serine residue comprising culturing, in a medium, transformed host cells that produce a recombinant atrial natriuretic peptide comprising a serine residue and a byproduct polypeptide comprising an O-acetylserine residue in place of a serine residue; adding to said medium at least one of histidine, methionine or glycine in an amount effective to reduce said byproduct formation; and reducing formation of said byproduct polypeptide. Furthermore, the Yabuta '340 patent does not disclose a method for producing a polypeptide comprising a serine residue comprising: culturing, in a medium, transformed host cells that produce a recombinant atrial natriuretic peptide comprising a serine

residue and a byproduct polypeptide comprising an O-acetylserine residue in place of a serine residue; adding at least one of histidine, methionine or glycine to the medium in an amount effective to reduce said byproduct formation; and reducing the formation of said byproduct polypeptide.

Previously, the Examiner cited claim 1 of the Yabuta '340 patent for the proposition that "Yabuta et al. teaches a process for the production of a protein (including artrial natriuretic peptide) comprising culturing E. coli host cells transformed with a plasmid capable of expressing the protein." (See Office Action dated October 20, 2004 at page 2). However, claim 1 of the Yabuta '340 patent does not disclose adding to the culture medium at least one of histidine, methionine or glycine in an amount effective to reduce said byproduct formation, nor does claim 1 of the Yabuta '340 patent disclose reducing formation of said byproduct polypeptide.

The Examiner also stated, "[t]he broth or media used in during the incubation or growth step of the host cell E. coli comprises 2.0g/L of L-methionine (see Example 3)." (See Office Action dated October 20, 2004 at pages 2-3). However, as discussed with the Examiner during the interview, Example 3 of the Yabuta '340 patent does not disclose a method for reducing formation of a byproduct polypeptide comprising an O-acetylserine residue in place of a serine residue comprising culturing, in a medium, transformed host cells that produce a recombinant atrial natriuretic peptide comprising a serine residue and a byproduct polypeptide comprising an O-acetylserine residue in place of a serine residue; adding to said medium at least one of histidine, methionine or glycine in an amount effective to reduce said byproduct formation; and reducing the formation of said byproduct polypeptide. Furthermore, the Yabuta '340 patent does not disclose a method for producing a polypeptide comprising a serine residue comprising: culturing, in a medium, transformed host cells that produce a recombinant atrial natriuretic peptide comprising a serine residue and a byproduct polypeptide comprising an O-acetylserine residue in place of a serine residue; adding at least one of histidine, methionine or glycine to the medium in an amount effective to reduce said byproduct formation; and reducing the formation of said byproduct polypeptide.

Regarding claim 11, the Yabuta '340 patent does not disclose a culture medium comprising: transformed host cells that produce a recombinant polypeptide comprising a serine residue and a byproduct polypeptide comprising an O-acetylserine residue in place of a serine residue; at least one of histidine, methionine or glycine added to the medium in an amount effective to reduce formation of a byproduct polypeptide comprising O-acetylserine residue in place of a serine residue; and a reduced formation of said byproduct polypeptide as compared with a control medium with no histidine, methionine or glycine added.

For at least the foregoing reasons, Applicants respectfully submit that the Yabuta '340 patent fails to anticipate claims 3-6 and 8-12, under 35 U.S.C. § 102(b), and respectfully request removal of the rejections under § 102(b) as anticipated by the Yabuta '340 patent from the application.

The Office Action states that claims 3-6 and 9-11 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,169,772, issued to Zimmerman et al. ("the Zimmerman '772 patent"). Applicants respectfully submit that the Zimmerman '772 patent fails to disclose all of the elements and limitations of the present invention as currently amended herein.

At the outset, Applicants note that claim 7 has been canceled by the current amendment, and the limitation of claim 7 has been incorporated into claims 9-10. Claim 7 was not rejected over the Zimmerman '772 patent.

The Zimmerman '772 patent does not disclose a method for reducing formation of a byproduct polypeptide comprising an O-acetylserine residue in place of a serine residue comprising: culturing, in a medium, transformed host cells that produce a recombinant atrial natriuretic peptide comprising a serine residue and a byproduct polypeptide comprising an O-acetylserine residue in place of a serine residue; adding to said medium at least one of histidine, methionine or glycine in an amount effective to reduce said byproduct formation; and reducing the formation of said byproduct polypeptide. Furthermore, the Zimmerman '772 patent does not disclose a method for producing a polypeptide comprising a serine residue comprising: culturing, in a medium, transformed host cells that produce a recombinant atrial natriuretic peptide

comprising a serine residue and a byproduct polypeptide comprising an O-acetylserine residue in place of a serine residue; adding at least one of histidine, methionine or glycine to the medium in an amount effective to reduce said byproduct formation; and reducing the formation of said byproduct polypeptide.

Regarding claim 11, the Zimmerman '772 patent does not disclose a culture medium comprising: transformed host cells that produce a recombinant polypeptide comprising a serine residue and a byproduct polypeptide comprising an O-acetylserine residue in place of a serine residue; at least one of histidine, methionine or glycine added to the medium in an amount effective to reduce formation of a byproduct polypeptide comprising O-acetylserine residue in place of a serine residue; and a reduced formation of said byproduct polypeptide as compared with a control medium with no histidine, methionine or glycine added.

Accordingly, Applicants respectfully submit that the Zimmerman '772 patent fails to anticipate claims 3-6 and 9-12, under 35 U.S.C. § 102(b), and respectfully request removal of the rejections under § 102(b) as anticipated by the Zimmerman '772 patent from the application.

Information Disclosure Statement

Concurrently with this response, Applicants submit herewith a Second Supplemental Information Disclosure Statement. Applicants respectfully request the Examiner to consider this Second Supplemental Information Disclosure Statement as well as Applicants previously submitted First Supplemental Information Disclosure Statement filed on October 22, 2004 and Applicants Information Disclosure Statement filed on May 10, 2002.

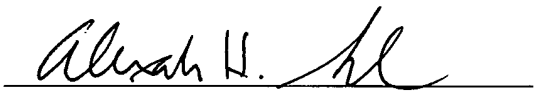
CONCLUSION

Applicants respectfully request consideration of the above remarks. In view of the above remarks, early notification of a favorable consideration is respectfully requested.

A check is enclosed in the amount of $1,810.00, which covers the three-month extension of time fee and the Request for Continued Examination. The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 50-0206.

Respectfully submitted,

Dated: April 20, 2005

By: 

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